UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF VIRGINIA
NORFOLK DIVISION

In re: ZETIA (EZETIMIBE) ANTITRUST LITIGATION	
This Document Relates To: *All Actions*	Case No. 2:18-md-2836

DEFENDANTS' MEMORANDUM IN SUPPORT OF JOINT MOTION TO EXCLUDE PROPOSED EXPERT OPINIONS AND TESTIMONY OF PLAINTIFFS' GENERIC LAUNCH TIMING EXPERTS JON CLARK AND TODD CLARK

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INTRODUCTION

To establish the essential elements of antitrust injury and causation, as well as the damages they seek, Plaintiffs must show that but-for the alleged No-Authorized Generic ("no-AG") commitment, Glenmark and other generic manufacturers would have obtained regulatory approval and launched generic ezetimibe in competition with Merck's branded Zetia product earlier than they did in the real world. *See* Glenmark Summ. J. Br. at Argument § III.[1] If, for example, Plaintiffs cannot prove that Glenmark or another generic firm would have been able to launch earlier than December 12, 2016, then they cannot establish harm resulting from the alleged exchange of a payment for delay. Indeed, the inability to prove that generic entry would have occurred in the absence of the challenged agreement was what doomed the plaintiffs' case in *In re Nexium Antitrust Litigation*, which is the only reverse payment case ever to have been tried to a jury. In an effort to make this necessary counterfactual showing in this case, Plaintiffs rely, in part, on two experts, Jon Clark and Todd Clark, who opine on the timing of launch by Glenmark and other suppliers of generic ezetimibe had Glenmark secured an earlier entry date. But neither expert can help Plaintiffs carry their evidentiary burden because each of their opinions fails to satisfy the requirements of *Daubert v. Merrell Dow Pharmaceuticals*, 509 U.S. 579 (1993) and Federal Rule of Evidence 702.

Plaintiffs rely on Jon Clark, a former official at the Food and Drug Administration ("FDA"), to support their allegations that, in the but-for world where no alleged payment for delay was made, Glenmark would have sought and obtained regulatory approval for its generic

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[1] "Glenmark" refers collectively to Defendants Glenmark Pharmaceuticals, Ltd. and Glenmark Generics Inc., USA, incorrectly identified as Glenmark Generics, Inc. USA, and "Merck" refers collectively to Defendants Merck & Co., Inc., Merck Sharp & Dohme Corp., Schering-Plough Corp., Schering Corp., and MSP Singapore Co. LLC.

Zetia product earlier than it did. Jon Clark's opinions are unreliable and inadmissible for three independent reasons.

First, Jon Clark purports to speak to how a "*reasonable generic firm in Glenmark's position*" would have acted in the but-for world. But his opinions are unreliable *ipse dixit* because he has no basis in his experience or the record to support his opinion concerning how a reasonable generic firm in the same position as Glenmark would have behaved in terms of seeking regulatory approval had its entry date been earlier. Nor has he identified any methodology that he employed to reach his conclusions. Instead, Jon Clark, who has never worked at a generic drug company or had responsibility for decision-making with respect to a generic drug manufacturer's filing strategy, testified that his opinion is based on nothing more than his own expectations. Those expectations have no factual support and must be excluded.

Second, Jon Clark's conclusion about the timing of Glenmark's ability and readiness to launch from a regulatory perspective in the but-for world is based on his views about how a "reasonable generic firm" would have behaved. He admits, however, that in the actual world Glenmark did not act the way he would expect a reasonable generic firm to act. In the real world, rather than seek regulatory approval at the earliest possible opportunity, Glenmark took the time to develop a new process for manufacturing the active pharmaceutical ingredient ("API") for ezetimibe before seeking final approval and then elected to add a third-party source of API only after Glenmark secured final approval. Those facts are inconsistent with what Jon Clark's opinion would predict, and in his deposition he could not explain why Glenmark did not act in the way he would expect. Because Jon Clark's opinion as to what a "reasonable generic firm" would have done cannot be reconciled with the facts, it fails to meet the *Daubert* standard.

Third, the only relevant question to be answered by Jon Clark is whether *Glenmark* would have obtained regulatory approval earlier had it secured an earlier entry date. But because Jon Clark cannot say that Glenmark and a reasonable generic firm (as he defines it) would have acted in the same way in the but-for world, his opinion about how a hypothetical generic firm he constructed out of whole cloth—but not Glenmark—would have acted is irrelevant and fails to fit the case. Rule 702 and *Daubert* require the Court to exercise its gatekeeping function and exclude precisely this type of unhelpful expert testimony.

Plaintiffs' other launch timing expert—Todd Clark, a pharmaceutical industry business consultant—was asked by Plaintiffs' counsel to address the question of whether Teva and Sandoz, two other generic manufacturers, would have been motivated to obtain regulatory approval and launch their generic ezetimibe products more quickly if Glenmark had secured an earlier entry date in the but-for world. His opinions are inadmissible, as well, for two independent reasons.

First, in Todd Clark's nonlitigation consulting practice, he uses self-described "sophisticated modeling"—namely a "Monte Carlo analysis"—when evaluating the likelihood of other generic launches. Not only did Todd Clark fail to use any of those models for his analysis in this case, he "didn't build a model" at all. *Daubert* instructs that courts should not allow the jury to be exposed to experts who, like Todd Clark here, have failed to bring the same rigor and methods to their litigation testimony that they use in their professional work. Todd Clark's opinion fails this test and should be excluded on this basis alone.

Second, Todd Clark's deposition testimony exposed a critical missing step in his opinion. Despite opining that the presence of so-called acceleration clauses[2] were crucial to the timing of generic entry, he testified that he does not know, and is not offering an opinion on, whether Teva and Sandoz would have negotiated acceleration clauses in their respective settlements with Merck in the but-for world. Nor is there any other evidence in the record concerning these clauses in the Teva and Sandoz agreements. Without this critical link, Todd Clark has no proper basis to opine that Teva and Sandoz would have been authorized to launch their generic ezetimibe products earlier in the counterfactual world. Indeed, absent an opinion that such acceleration clauses would have been included in the Teva and Sandoz agreements, they would have been foreclosed from earlier entry. Because Todd Clark's analysis is missing an essential piece, his opinion is unreliable and inadmissible.

In sum, the opinions by Jon Clark and Todd Clark suffer from multiple fundamental flaws, each of which requires exclusion.

RELEVANT BACKGROUND

I. Overview of ANDA and DMF Filings.

To sell a generic pharmaceutical product in the United States, a generic pharmaceutical manufacturer must obtain approval from the FDA of an Abbreviated New Drug Application ("ANDA"). J. Clark Rpt. ¶ 29, Fee Decl. Ex. 1.[3] As part of an ANDA, a generic manufacturer must identify, among other things, the API supplier and make reference to the Drug Master File ("DMF") for the API. *Id*. ¶ 25. A DMF file is a separate submission to FDA by the maker of an

[2] "Acceleration clauses" typically provide that if a certain triggering event occurs, such as Glenmark launching its generic ezetimibe product, other generics have their entry dates "accelerated" so they may enter earlier than otherwise permitted under their licensing agreement with the brand.

[3] Exhibit numbers refer to exhibits in the accompanying declaration of R. Brendan Fee.

API that provides information about the API manufacturer's facilities, processes, and chemistry. *Id*. ¶¶ 25, 43-45. A generic manufacturer may make its own API and thus file its own DMF or it may source API from a third party and submit its ANDA with reference to the third party's DMF. *See id.* ¶¶ 43-45.

In deciding whether to approve an ANDA, the FDA will review both the ANDA and DMF files. *Id*. ¶ 45. If a DMF file is deemed inadequate by FDA, the ANDA cannot be approved. *Id*. ¶ 27. Once an ANDA is approved, a manufacturer may decide to change its API supplier. In that case, the manufacturer must submit a request to FDA for approval to use an alternative API supplier and reference the API supplier's DMF. *Id*. ¶ 27. The FDA at no point in its review or approval processes makes any assessment of whether the processes specified in an ANDA or DMF will enable a manufacturer to make the quantities of product needed for commercial launch. J. Clark Tr. at 28:22-29:5, Ex. 2.

II. Glenmark's ANDA Filing and API Development.

On October 25, 2006, Glenmark was the first to file its ANDA for ezetimibe. J. Clark Rpt. ¶ 64, Ex. 1. Despite being the first to file, Glenmark faced multiple manufacturing impediments as it attempted to develop a manufacturing process for its API that could be scaled up for commercial use. *See, e.g.*, Glenmark Summ. J. Br. at Smt. of Undisputed Facts ¶¶ 38-42. In connection with its ANDA submission, Glenmark also submitted a DMF for API that Glenmark internally referred to as "Process 1." J. Clark Rpt. ¶ 72, Ex. 1; Lindsey Rpt. at A-1, Ex. 3 (Appendix A contains a timeline of the "Regulatory and [Joint Steering Committee] for Glenmark/Par"). On April 24, 2009, FDA issued tentative approval of Glenmark's ANDA that

used Glenmark's Process 1 DMF. Lindsey Rpt. at A-1, Ex. 3.[4] Glenmark's Process 1 API, however, could not be scaled up to manufacture sufficient quantities of ezetimibe API. *Id.* ¶¶ 33-43; *see also* J. Clark Rebuttal ¶ 9, Ex. 4. Glenmark thus sought to develop more efficient ways of synthesizing ezetimibe API so that it could be scaled up, and on August 5, 2011, submitted a second DMF to FDA that included Glenmark's "Process 2" API. Lindsey Rpt. ¶ 46, Ex. 3. On October 10, 2014, Glenmark sought final approval of its ANDA using Process 2 and on June 26, 2015, FDA issued final approval. *Id*. at A-3 to A-4.

In 2014, Glenmark determined that it would purchase additional API from a third-party supplier named MSN. *Id.* ¶¶ 50-52. MSN had filed a separate DMF using a process for manufacturing that MSN had developed. *Id*. ¶¶ 48-52; J. Clark Rpt. ¶ 93, Ex. 1. To use MSN's API, Glenmark submitted a Post Approval Supplement ("PAS") on July 7, 2015, which FDA approved on September 3, 2015. Lindsey Rpt. ¶ 78, Ex. 3; *see also id*. at A-3 to A-4, Ex. 3. Ultimately, Glenmark launched on December 12, 2016 using API from MSN and from Glenmark's Process 2. *E.g.*, *id*. ¶ 82.

III. Jon Clark's Opinions on Glenmark's Regulatory Filing Strategy.

Jon Clark is a former FDA official who has never worked at a generic firm or had responsibility for decision-making with respect to an ANDA filing strategy. J. Clark Rpt. ¶¶ 3-4, Ex. 1; J. Clark Tr. at 81:23-82:11, Ex. 2. Nonetheless, Plaintiffs engaged him to evaluate three regulatory filing scenarios that involve different times at which Glenmark could have filed for and obtained final approval depending on which of the three DMFs (Process 1, Process 2, or

[4] The FDA may either issue tentative or final approval of an ANDA. A tentative approval does not allow the applicant to market the product; only after final approval is requested and issued can a manufacturer begin to market the product. J. Clark Rpt. ¶¶ 29-30, Ex. 1.

MSN) Glenmark decided to reference in its request for final approval. J. Clark Rpt. ¶¶ 13, 104-109, Ex. 1.

In his report, Jon Clark presents two regulatory filing strategies that he believes Glenmark could have pursued. The first has Glenmark securing final approval in January 2011 with an ANDA that references only Glenmark's Process 1 DMF. J. Clark Rebuttal ¶ 50, Ex. 4. The second has Glenmark securing final approval three years later, in June 2014, with an ANDA that references Glenmark's Process 1 and 2 DMFs as well as MSN's DMF. *Id*. Although he believes a "reasonable generic manufacturer in Glenmark's position" would "request final approval at its first opportunity," J. Clark Rpt. ¶ 108, Ex. 1, Jon Clark concedes that Glenmark did not do that in the actual world, J. Clark Tr. at 110:11-111:12, 113:21-115:6, Ex. 2. In fact, Glenmark did not pursue either of the regulatory approval filing strategies Jon Clark identifies. Rather, Glenmark elected to develop its Process 2 API prior to seeking final approval and only sought to add MSN as a third-party API supplier after Glenmark secured final approval. Lindsey Rpt. ¶¶ 46, 74-78, Ex. 3. Despite the fact that Glenmark's actual conduct was inconsistent with his prediction about what it would do, Jon Clark admitted that he made no attempt to investigate the reasons for Glenmark's regulatory filing strategy in the real world. J. Clark Tr. at 110:11-111:12, 113:21-115:6, Ex. 2.

IV. Todd Clark's Opinions on the Timing of Entry by Teva and Sandoz.

Todd Clark is a business consultant who Plaintiffs retained to offer an opinion as to the economic incentives of generic firms to launch a generic ezetimibe product and, specifically, whether Teva and Sandoz[5] would have been motivated to obtain regulatory approval and launch

[5] Todd Clark admitted that he has no opinion regarding the timing of regulatory approval or launch by ANDA filers for ezetimibe other than Teva and Sandoz. T. Clark Tr. at 107:11-19, Ex. 5.

their versions of generic ezetimibe earlier had Glenmark secured an earlier entry date. T. Clark Rpt. ¶¶ 9-10, Ex. 6. Unlike Jon Clark, Todd Clark is not a former FDA official and he does not purport to render an opinion on whether Teva or Sandoz would have changed their regulatory filing strategies in the but-for world. Instead, Todd Clark offers a more generalized opinion that there were strong economic incentives for manufacturers to launch generic versions of ezetimibe and that, given these incentives, Teva and Sandoz would have sought final regulatory approval and launched their generics versions of ezetimibe earlier if possible. *Id*. ¶ 15; *see also id*. at 28.

As part of Todd Clark's nonlitigation consulting practice, he has advised clients on predicting "the extent and timing of generic entry." *Id*. ¶ 4. To complete this type of analysis, he employs "sophisticated modeling" that includes "deterministic modeling" and "Monte Carlo analysis." T. Clark Tr. at 62:15-65:13, Ex. 5. Deterministic modeling involves calculating the probability of additional entrants and an associated price drop. *Id*. at 64:12-20. Monte Carlo analysis involves building a model that factors in the probability of certain events to determine the various ways a scenario could unfold and the probability of each outcome. *Id*. at 64:21-65:3, 181:5-182:5. On his resume, Todd Clark highlights his experience with Monte Carlo analysis to "[d]esign numerous forecasting and other probability-based methods." T. Clark Rpt., CV at 4, Ex. 6; *see also id*. at 2 (listing presentation in 2016 at conference on the topic of Monte Carlo analysis); *id*. at 3-4 (listing additional experience using Monte Carlo analysis). Todd Clark has also used Monte Carlo analysis in his academic publications related to the pharmaceutical industry. T. Clark Tr. at 175:22-176:16, 181:5-182:5, Ex. 5. Despite the significance of these models in Todd Clark's nonlitigation work, he did not use Monte Carlo analysis or deterministic modeling here; in fact, he "didn't build a model" at all for his opinions in this case. *Id*. at 94:4-96:14, 102:12-18.

Notwithstanding this lack of any discernable methodology, Todd Clark opines that Teva and Sandoz would have obtained final regulatory approval and launched earlier in the but-for world. [redacted] T. Clark Rpt. ¶ 42, Ex. 6. The existence of these provisions in the but-for world is essential to Todd Clark's opinions. Indeed, Todd Clark hypothesizes that if acceleration clauses were used in the but-for world, Teva and Sandoz would have been permitted to launch earlier and would have planned to do so. *Id*. ¶¶ 55, 61 (Teva); *id*. ¶ 67 (Sandoz); *see also* T. Clark Rebuttal ¶¶ 20-22, Ex. 4. At his deposition, however, Todd Clark admitted that he did not know and thus could not offer an opinion on whether the same acceleration clauses used in the real world would have been present in the but-for world. T. Clark Tr. at 202:16-203:11, Ex. 5.

LEGAL STANDARDS

Federal Rule of Evidence 702 imposes a "special obligation" on the district court to ensure that expert testimony is both reliable and relevant, and this "gatekeeping" role applies to all types of expert testimony. *Kumho Tire Co. v. Carmichael*, 526 U.S. 137, 141, 147 (1999). "[T]he trial judge must ensure that any and all scientific testimony or evidence admitted is not only relevant, but reliable." *Daubert*, 509 U.S. at 589. This requires that the court make "certain that an expert, whether basing testimony upon professional studies or personal experience, employs in the courtroom the same level of intellectual rigor that characterizes the practice of an expert in the relevant field." *Kumho Tire Co.*, 526 U.S. at 152. As the proponents of purported expert testimony from Jon Clark and Todd Clark, Plaintiffs have the burden to establish that their testimony is admissible by a preponderance of the evidence. *Cooper v. Smith & Nephew, Inc.*, 259 F.3d 194, 199 (4th Cir. 2001).

In assessing reliability, a court is to examine "whether the reasoning or methodology underlying the expert's proffered opinion . . . is supported by adequate validation to render it trustworthy." *Westberry v. Gislaved Gummi AB*, 178 F.3d 257, 261 (4th Cir. 1999) (citing *Daubert*, 509 U.S. at 592). Determining whether testimony is relevant and will help the trier of fact requires the court to assess whether an expert's opinion has "a valid scientific connection to the pertinent inquiry." *Daubert*, 509 U.S. at 591; Fed. R. Evid. 702(a). Often referred to as the "fit" requirement, this criteria ensures that an expert's opinion is "sufficiently tied to the facts of the case [such] that it will aid the jury in resolving a factual dispute." *Daubert*, 509 U.S. at 592 (citations omitted). The Fourth Circuit has stressed the importance of ensuring that experts "offer an opinion that fits the case at hand, not some other, hypothetical case," because opinions that "ignore[] key evidence veer[] into speculation." *Trana Discovery, Inc. v. S. Research Inst.*, 915 F.3d 249, 255 (4th Cir. 2019).

ARGUMENT

I. Jon Clark's Opinions Are Unreliable and Do Not Fit the Case.

Jon Clark's opinions are inadmissible for three independent reasons. First, Jon Clark supplies no methodology beyond his own say-so to reach his conclusions, rendering his opinions impermissible *ipse dixit*. Second, Jon Clark's opinion about what a reasonable company would have done is unreliable because it is inconsistent with the facts as to what Glenmark, presumably a reasonable generic company, did in the actual world. Third, since Jon Clark cannot say that Glenmark and a reasonable company would have done the same thing in the real or but-for worlds, his opinion about the actions of a hypothetical reasonable generic firm would be unhelpful to the jury and fail to fit the facts of the case.

A. Jon Clark's Conclusions Are Inadmissible *Ipse Dixit*.

Jon Clark provides no methodology or basis for his belief that a "reasonable generic firm" would have acted in the way he theorizes beyond his say-so. *Daubert*, however, requires more for an expert opinion to be admissible. To be reliable, expert opinion must "be connected to existing data by something more than the 'it is so because I say it is so' of the expert." *Holesapple v. Barrett*, 5 F. App'x 177, 180 (4th Cir. 2001) (affirming exclusion of *ipse dixit* opinion where expert failed to consider facts associated with an underlying boating accident); *see also* Fed. R. Evid. 702 cmt. ("The trial court's gatekeeping function requires more than simply 'taking the expert's word for it.'" (citation omitted)).

Jon Clark's opinion about how a "reasonable generic firm" would have operated is purportedly based on how he thinks generic firms should operate in light of his experience. J. Clark. Tr. at 112:2-9, Ex. 2. Yet Jon Clark has never worked at a generic firm, has never had decision-making responsibility for a generic firm's strategy with respect to any ANDA filing, and, critically, does not know why Glenmark acted the way it did. *Id*. at 81:23-82:6, 114:13-24, 115:1-6. Against this backdrop, Jon Clark's opinion that "a reasonable generic manufacturer in Glenmark's position" would have acted differently is classic *ipse dixit*. He has no basis to say, whether from his own experience or the record in this case, that Glenmark would have decided to seek final approval in the but-for world earlier than it did in the real world. Expert opinion grounded solely in an expert's "say so" is inadmissible. *In re Namenda Direct Purchaser Antitrust Litig.*, 331 F. Supp. 3d 152, 171-72 (S.D.N.Y. 2018) (excluding expert on launch timing of later generic filers as *ipse dixit* where expert failed to analyze the market and corporate conditions that might have impacted the later generic filers to launch earlier in the but-for world); *see also Cooper*, 259 F.3d at 200 (affirming exclusion of expert where expert "asserted what amounted to a wholly conclusory finding based upon his subjective beliefs rather than any

valid scientific method"); *In re Trasylol Prod. Liab. Litig.*, 709 F. Supp. 2d 1323, 1347 (S.D. Fla. 2010) (excluding FDA expert testimony where opinion offered broad opinion that was "not connected to the underlying facts in any apparent way" and therefore "lack[ed] regulatory expert analysis").

In short, Jon Clark cannot tell the jury in this case that Glenmark would have made different regulatory filing decisions in the but-for world "because I say it is so." *Holesapple*, 5 F. App'x at 180. Rule 702 prohibits such *ipse dixit*.

B. Jon Clark's Opinions Are Unreliable Because They Are Inconsistent With the Facts.

Jon Clark's opinion about what would have happened with respect to Glenmark's ezetimibe ANDA in the but-for world is predicated on his belief about how "reasonable generic firms" behave. The anchor of his opinion is the implicit assumption that Glenmark would act in the way Jon Clark would expect a reasonable generic firm to act. But Jon Clark lost that mooring when he admitted that Glenmark's actions in the real world were inconsistent with how he expected a reasonable generic firm to act. As a result, Jon Clark's opinion as to the behavior of a "reasonable generic firm" in the but-for world are unreliable and should be excluded.

An expert cannot "speculate in fashions unsupported by, and in this case indeed in contradiction of, the uncontroverted evidence in the case." *Newman v. Hy-Way Heat Sys., Inc.*, 789 F.2d 269, 270 (4th Cir. 1986); *see also Tyger Const. Co. v. Pensacola Const. Co.*, 29 F.3d 137, 143 (4th Cir. 1994) (excluding expert where opinion was "based on assumptions not supported by the record"). Here, Jon Clark admitted that his opinion about how Glenmark should act is contradicted by the record evidence. Specifically, Jon Clark testified that he would have expected a reasonable generic firm to have obtained approval in the real world at its earliest opportunity. J. Clark Tr. at 110:11-21, Ex. 2. Glenmark, however, did not follow this path.

Instead, it sought to first develop its Process 2 API before seeking final regulatory approval. And, only after Glenmark secured final regulatory approval did it then seek to add MSN as a third-party API supplier. Jon Clark does not address why Glenmark made the decision to proceed in this fashion and he admitted that he does not "know why [Glenmark] didn't do what I would expect them to do." *Id*. at 114:6-9. In fact, he repeatedly sought to distance himself from the reasons why Glenmark in the real world acted in ways that are contrary to what he would expect. *Id*. at 113:4-7 (testifying that he is not "offer[ing] any judgment as to whether Glenmark is reasonable. I simply don't know why they didn't do what I would expect them to do."); *see also id*. at 111:9-12 (testifying that he is not offering an opinion "as to why Glenmark acted one way or another").

Moreover, Jon Clark made no attempt to understand Glenmark's decision-making process and why it was different from what he would expect. Nowhere in either of his reports does Jon Clark undertake any sort of analysis of why it was that Glenmark chose the regulatory filing strategy it did—with multiple DMF filings and a request to approve MSN's DMF *after* Glenmark secured final approval. Nor does he have an explanation for how circumstances may have changed in the but-for world such that Glenmark would choose to act in a way he expects.

Simply put, Jon Clark's inability to say that Glenmark—which he appears to assume is a reasonable generic firm—acted as he would expect in the real world means that his opinion about how a reasonable generic firm in Glenmark's position would have behaved in the counterfactual world is without any basis. *See Belville v. Ford Motor Co.*, 919 F.3d 224, 234 (4th Cir. 2019) (affirming exclusion of expert opinion where testing process "seemed artificially induced to produce a desired result and did not reflect [the] real-world"). Because Jon Clark's

opinion about the conduct of Glenmark in the but-for world is inexplicably inconsistent with the facts, it is unreliable and thus inadmissible.

C. Jon Clark's Opinions About How a Reasonable Generic Firm Should Have Acted Do Not Fit the Case.

Because Jon Clark cannot say that Glenmark would have acted in the but-for world in the same way that a reasonable generic firm (as he conceives it) would act, he is, at best, left to offer an opinion about a hypothetical reasonable generic firm that is irrelevant and unhelpful to the jury in understanding the circumstances confronting Glenmark in this case. This opinion fails the fit element of Rule 702 and must be excluded.

Jon Clark's failure to tie his opinions to the facts of this case is evident from the different positions he took in his reports and during his deposition. In his reports, Jon Clark opines that a "reasonable generic manufacturer in Glenmark's position" would have sought final regulatory approval of its ANDA in the but-for world sooner than Glenmark did in the real world. J. Clark Rpt. ¶¶ 100, 107-09, Ex. 6. But, at his deposition he backpedaled and downplayed any connection between his opinions and Glenmark's actions, testifying that he is not "offer[ing] any judgment as to whether Glenmark is reasonable," nor is he offering an opinion as to whether Glenmark qualifies as a "reasonable generic firm" as he defines it. J. Clark Tr. at 113:21-114:9, 114:13-24-115:6, Ex. 2. And, as noted above, Jon Clark does not know why "Glenmark didn't do what I would expect them to do." *Id*. at 110:11-21; *see also id*. at 111:9-12.

Because his opinion does not account for the facts unique to Glenmark and he cannot conclude that Glenmark fits the mold of the hypothetical "reasonable generic firm" as he envisions it, Jon Clark's opinions are unhelpful to the jury. *In re TMI Litig.*, 193 F.3d 613, 670 (3d Cir. 1999) (affirming decision to exclude expert's use of "water model" to show radioactive plume travel for lacking fit because the model did not exactly simulate the radioactive plume

released at the time of the Three Mile Island accident). Opinions like Jon Clark's here fail the fit requirement precisely because they "amounted to abstract conclusions not adequately grounded in the facts." *El Aguila Food Prod., Inc. v. Gruma Corp.*, 131 F. App'x 450, 454 (5th Cir. 2005) (affirming exclusion of causation expert in antitrust case where expert failed to review relevant facts in the record that would have allowed the expert to connect alleged shelf-space allocation to plaintiffs' claimed harm).

Indeed, the Fourth Circuit has cautioned that experts fail the fit requirement where they offer, as Jon Clark does here, opinions about a "hypothetical case" that are untethered to the record. *Trana Discovery, Inc.*, 915 F.3d at 255. Absent any connective tissue between Jon Clark's "hypothetical case" and Glenmark's behavior, the jury will be left to guess as to whether Glenmark might have followed any of the filing strategies Jon Clark contends were available. Abstract expert opinion testimony that "does not apply to the specific facts of the case," like the opinion here, fails to satisfy the fit requirement of Rule 702 and *Daubert* and thus "should not be admitted." *Concord Boat Corp. v. Brunswick Corp.*, 207 F.3d 1039, 1056 (8th Cir. 2000) (finding that expert testimony regarding monopoly power, causation, and damages failed the fit requirement where expert "construct[ed] a hypothetical market which was not grounded in the economic reality . . . , for it ignored inconvenient evidence."); *Wise v. C.R. Bard, Inc.,* No. 2:12-cv-01378, 2015 WL 521202, at *8 (S.D.W. Va. Feb. 7, 2015) (holding that opinion about degradation of pelvic mesh "*generally*" did not fit the facts because it did not include "any connection" to the expert's opinions about the pelvic mesh in the specific patient); *see also In re TMI Litig.*, 193 F.3d at 674 (3d Cir. 1999) (affirming decision to exclude another expert on fit grounds where "connection between [expert's] testimony and a crucial fact in issue, *i.e.*, whether

[plaintiffs] were exposed [to high levels of radiation,] was tenuous at best because he could not testify" as to how much radiation was actually released).

In sum, Jon Clark's opinions are impermissible *ipse dixit*, unreliable, and unhelpful. This Court should exercise its gatekeeping function and exclude his opinions and testimony.

II. Todd Clark's Opinions Regarding the Alternative Entry Dates of Teva and Sandoz Are Unreliable and Inadmissible.

Todd Clark—the business consulting expert retained by Plaintiffs to opine on the incentives affecting the but-for timing of entry of Teva and Sandoz—is equally unreliable, but for different reasons. One of the key gatekeeping responsibilities under *Daubert* is to "make certain that an expert, whether basing testimony upon professional studies or personal experience, employs in the courtroom the same level of intellectual rigor that characterizes the practice of an expert in the relevant field." *In re Lipitor (Atorvastatin Calcium) Mktg., Sales Practices & Prod. Liab. Litig. (No II) MDL 2502*, 892 F.3d 624, 631 (4th Cir. 2018) (quoting *Kumho Tire Co.*, 526 U.S. at 152). Todd Clark's opinions unquestionably fail this test.

Todd Clark claims that to reach his opinions he employed "the same methodology [he uses] in [his] consulting, academic, and professional activities." T. Clark Rpt. ¶ 12, Ex. 6. During his deposition, however, it became clear that Todd Clark did no such thing. In describing his experience in this case, Todd Clark cites his work as a consultant in the pharmaceutical sector, which includes experience serving as a consultant to help clients "predict the extent and timing of generic entry." *Id*. ¶ 4. When Todd Clark seeks to evaluate subsequent generic entry in his consulting practice, he uses "sophisticated modeling." T. Clark Tr. at 62:15-65:13, Ex. 5. Two types of models Todd Clark uses in his private practice include "deterministic modeling," which includes calculating the probability of additional entrants and an associated price drop, and "Monte Carlo analysis," which factors in the probability of certain events to a scenario. *Id*.

at 64:12-20-65:3, 181:5-182:5. Todd Clark highlights on his curriculum vitae his experience using Monte Carlo analysis to "[d]esign numerous forecasting and other probability-based methods," T. Clark Rpt., CV at 4, Ex. 6, and he has used Monte Carlo analysis in his academic writing, T. Clark Tr. at 175:22-176:16, 181:5-182:5, Ex. 5.

Despite his reliance on "sophisticated modeling" when working as a nonlitigation consultant and in his academic writings, Todd Clark "didn't build a model" in this case to develop his opinion that Teva and Sandoz would have launched earlier in the but-for world. *Id*. at 94:4-96:14, 102:12-18. When asked if he used any of the models he uses in his consulting practice, Todd Clark admitted that he did not use either a deterministic model, *id*. at 102:12-15, or a Monte Carlo analysis, *id*. at 102:16-18. Thus, by his own admission, Todd Clark has simply failed to employ "in the courtroom the same level of intellectual rigor that characterizes the practice of an expert in the relevant field." *In re Lipitor*, 892 F.3d at 631 (citation omitted). Instead, he impermissibly relies on his own say-so in reaching his opinions in this case. *See Holesapple*, 5 F. App'x at 180.

This flaw was on full display when, during his deposition, Todd Clark testified that he is "roughly 95[%] plus" confident that Teva and Sandoz would have launched in the but-for world on the dates of their respective tentative approvals. T. Clark Tr. at 92:15-93:2, Ex. 5. Yet he admitted that he did no "quantitative model that says in there this is how I arrived at" his "roughly" 95% level of confidence. *Id*. at 96:23-97:1. The Court cannot even begin to apply the *Daubert* factors to this type of an opinion because the modeling Todd Clark testified he would need to use to arrive at this figure was never used. Thus, Todd Clark's opinions and testimony regarding the alternative launch timing of Teva and Sandoz are unreliable and should be excluded.

[redacted] T. Clark Rpt. ¶¶ 42, 55, 61, 67, Ex. 6; T. Clark Rebuttal Rpt. ¶¶ 20-22, Ex. 7. Yet, Todd Clark expressly does not offer an opinion as to whether Teva and Sandoz would have been able to secure settlements with acceleration clauses in the but-for world that Plaintiffs posit. T. Clark Tr. at 202:16-203:11, Ex. 5. Without such an opinion, Todd Clark cannot forge the critical link that would allow him to say that Teva or Sandoz could have launched earlier than they did in the real world. That is because, absent acceleration clauses in the but-for world, Teva and Sandoz could not have launched earlier—instead they would have remained sidelined by contract until the expiry of Merck's ezetimibe patent. *See Lee v. City of Richmond, Va.*, No. 12-cv-471, 2014 WL 5092715, at *7 (E.D. Va. Sept. 30, 2014) (excluding opinion where expert failed to supply "predicate for his opinion"). Having failed to supply the necessary underpinnings for his conclusion, Todd Clark's opinion and testimony concerning Teva and Sandoz's respective launch timing is unreliable and should be excluded for this reason as well.

CONCLUSION

For the foregoing reasons, Defendants respectfully request that the Court exclude all of the proffered expert opinions and testimony by Jon Clark and Todd Clark.

DATE: August 10, 2020

Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that on August 10, 2020, I electronically filed the foregoing with the Clerk of the Court using the CM/ECF system which will automatically email notification of such filing to all counsel of record. Any materials filed under seal have separately been served on local counsel for all parties.

DATED: August 10, 2020

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